

# **Exhibit A**

Case #3656 (05/01/00)

SONEX CORPORATION

The UltraSonex Toothbrushes &

SoniPick Flosser

*In-House*

- Claims based on clinical studies should be no broader than the clinical's conclusions and material limitations of a claim must be adequately disclosed.
- An advertiser must be able to substantiate all reasonable interpretations of its claims.
- An advertiser that provides product information to a catalog retailer has an obligation to insure that the product claims made in the catalog are supported.
- A testimonial claim, whether made by a consumer, professional/expert or celebrity, is the advertiser's claim and is subject to the same reasonable basis requirements as all other claims made by the advertiser.

#### BASIS OF INQUIRY

Tactica International, Inc. ("Tactica") challenged an advertising campaign for UltraSonex dental products, produced by Sonex International Corporation ("Sonex"), alleging that various efficacy, product performance and convenience claims were misleading to consumers and could not be supported by reliable evidence.

More than 30 claims were challenged in all. They fell into the following general categories:

#### I. UltraSonex Ultima Toothbrush and UltraSonex Plus Toothbrush:

- Exclusivity claims: that the [Ultima and/or UltraSonex Plus toothbrush] is the world's first and only ultrasonic toothbrush; is the newest and most advanced toothbrush you can buy, is the first and only toothbrush to combine the two most advanced technologies...ultrasound and...sonic vibration...;
- Clinical Performance claims:
  - i. Plaque Reduction claims: that the Ultima toothbrush...eliminates/reduces 97% of plaque with each three minute brushing. No other toothbrush can match that performance; remove[s] 97% of bacterial plaque in a single brushing;" reduces bacterial plaque by 97%,... in just four weeks, and can reduce plaque by 97% every time you brush (in 30 days).
  - ii. Bleeding Reduction claims: that UltraSonex and or the Ultima toothbrush reduces bleeding gums by 60% ...in just four weeks; interrupts the bacterial process, helping to reduce gum bleeding (60% after four weeks of use), can reduce gum bleeding by 60% in 30 days.
  - iii. Gingivitis Reduction claims: that the UltraSonex and/or Ultima reduces ...gingivitis by 28%—in just four weeks (30 days); can reverse the progression of gingivitis, which can lead to periodontal disease; interrupts the bacterial process, helping to reduce gingivitis (28% after four weeks of use, and 74% after six months of use), reduces gingivitis by 67% in a six month study."

The Sonex campaign also featured the following footnote:

"Results of a thirty day clinical trial conducted at a leading university teaching hospital. Subjects were instructed to brush twice daily for 3 minutes."

- Ultrasonic Penetration/Bacterial Removal claims: that UltraSonex toothbrushes or its ultrasonic component penetrate[s] the gumline to a depth of five (5) millimeters destroying the bacteria that cause gingivitis and bleeding gums; attack[s] bacteria and plaque 9mm below the gum line; help[s] remove nearly all bacterial plaque every time you brush; works below the gum line to remove plaque and bacteria; is far more effective than mechanical brushing because it disrupts the bacteriological activity that causes tooth decay and gum disease; dissolves away stains and plaque, and (together with sonic vibration) remove[s] virtually all bacterial plaque, not only in and around your teeth but deep below the gum line where other brushes can't reach.

## II. SoniPick Flosser

- Convenience claims: that the SoniPick Flosser reaches back molars, between teeth and deep within facial and lingual pockets where bacteria that cause gingivitis and gum disease hide and flourish, is ideal for removing plaque from areas even string floss can't reach, hiding behind braces, dental implants, under bridges crowns, and is an effective and easy new way to floss.
- Clinical Performance-Plaque Removal claims: that [SoniPick is] more than twice as effective as floss, with less than half the effort, 157% more effective than string floss, cleans better than string floss, removes the most stubborn plaque- no matter where it is hiding; and regular string floss removed only 23% of plaque, but SoniPick removed 59%.
- Salcs/Cost claims: that "the SoniPick costs just a fraction of those automatic flossers!"

### CHALLENGER'S POSITION

According to Tactica, the advertiser's exclusivity, clinical performance, and superior convenience claims for its UltraSonex dental products are misleading to consumers because: 1) other competitive toothbrushes also feature ultrasound and sonic frequency, 2) the advertiser's testing does not support the claims in its advertising, and 3) the claims are contradicted by reliable industry research.

#### I. The UltraSonex Ultima Toothbrush and UltraSonex Plus Toothbrush:

As a general matter, stated the challenger, Sonex does not clarify which of its two different UltraSonex toothbrush models were involved in the submitted studies. The UltraSonex Ultima toothbrush is a "materially different" toothbrush than its predecessors because it uses "sonic" vibration, making it unnecessary for the user to actually move the bristles. The different brushing motion and the addition of powered, lower speed sonic vibration in the Ultima could significantly impact any results produced manually with prior UltraSonex models. Therefore, the challenger asserted, studies that involved older UltraSonex models should not qualify as substantiation for claims relating to the current, powered UltraSonex Ultima.

#### Exclusivity claims

Tactica maintained that, the UltraSonex toothbrush is not the "newest, most advanced toothbrush you can buy," "the latest technological advancement today" and nor is it without equal in terms of performance (i.e. the claim: "No other toothbrush can match that performance").

As support for its assertion, the challenger pointed out that The Braun Oral B 3D Plaque Remover, combines "high-speed in-and-out pulsations" and "ultra-speed oscillations." This product was introduced in 1999, after the 1998 copyright featured in the Ultima instruction manual. Moreover, stated Tactica, the advertiser's studies never compared the UltraSonex to the Braun Oral-B 3D Plaque Remover or other electric toothbrushes models, introduced after 1993.<sup>1</sup> In fact, several studies demonstrate that the UltraSonex toothbrush performs at approximately the same level as a manual toothbrush.

#### Clinical Performance claims

While Tactica acknowledged that the advertiser's "30 day" Terezhalmy study had been introduced as substantiation for similar clinical performance claims in a 1995 NAD proceeding, it nonetheless questioned the reliability of the study and requested that NAD reconsider its validity.

First, the challenger noted, it is unclear whether the Terezhalmy study received the benefit of "peer review" from dental industry experts because the *Compendium* published the study six months before it first began to describe itself as "a peer-reviewed journal" in February-1995.

Peer review aside, the challenger maintained that the Terezhalmy study was fatally flawed because: participants apparently knew whether they were using an electric toothbrush or a manual toothbrush, the duration of brushing time by the subjects did not appear to be controlled, the test did not exclude other dental care products (i.e., toothpaste) and the UltraSonex group was "coached" or "directed" to brush in the precise areas where the plaque measures were to be taken.<sup>2</sup>

In addition, stated the challenger, the use of a “three minute” brushing time protocol in the *Terezhalmy study* exceeds the average one minute brushing time established in other studies. However, even if three minutes of brushing were appropriate, the manual toothbrush control group did not have a “built-in timer,” or controls to ensure compliance with a strict three minute regimen. Moreover, there was no evidence that manual brush users received any guidance as to where they should brush.

If these subjects brushed as they normally do, they brushed for about one minute, or approximately one-third the time of the UltraSonex group. This inequity in brushing time, the challenger explained, is problematic because a longer brushing time has been proven to result in more plaque removal with any toothbrush.

In addition, stated Tactica, the UltraSonex toothbrush group appeared to have benefited from the progressively increasing overnight plaque levels from baseline to day thirty. Because there is more plaque to remove during days 15-30, there was greater plaque reduction.<sup>3</sup> If anything then, the *Terezhalmy study* demonstrates the ineffectiveness of the UltraSonex toothbrush, because overnight plaque accumulations increased despite its use.

Finally, stated Tactica, the *Terezhalmy study* reported that the levels of gingivitis were low at baseline (less than 1 on the 0-3 Loe & Silness gingivitis index). This low level of gingivitis, postulated the advertiser, may be one of the reasons that other subsequent studies (i.e., the *Forgas-Brockmann study*) described the results of the *Terezhalmy study* as “clinically negligible.”

Therefore, the plaque, gingivitis and bleeding reduction claims associated with the *Terezhalmy study* are not supported.

In the alternative, stated the challenger, even if the NAD finds the *Terezhalmy study* to be credible, Sonex’s claims that “you can reduce plaque by 97% *each*” or “*every time* you brush,” fail to clearly and accurately disclose that the benefits followed 4 weeks (or 30 days) of brushing twice daily, for 3-minutes at a time; and that the plaque reduction was the before and after difference of a single brushing, as recommended by NAD’s 1995 Sonex decision.

Tactica also questioned the advertiser’s reliance on the *Van der Weijden study* and subsequent correlation to the *Terezhalmy study* as support for the claim “no other toothbrush can match that performance,” because no UltraSonex toothbrush was tested, different test protocols were used (i.e., no toothpaste), patients did not brush their own teeth and the study used a different plaque index (*Loe & Silness*).

Nonetheless, stated the challenger, even if the results of the two studies were comparable, the manual toothbrush in the *Van der Weijden study* removed an average of 95% (93% and 97%) of plaque from vestibular (outer) and lingual (inner) surfaces emphasized in the *Turesky Plaque Index* after three minutes. therefore, there is no performance advantage for the UltraSonex toothbrush.

Other well-controlled studies, including those sponsored by the advertiser, reached a similar conclusion. For example, the “six month” *Terezhalmy study*, a “continuation” of the “30 day” *Terezhalmy study*, concluded that “for plaque index and proportion of high plaque surfaces there was no group/time interaction and no difference the between toothbrush groups . . .” (manual toothbrush Group A and UltraSonex (Group B)).

The *Whitmyer, Terezhalmy study* (the “Geriatric” study), demonstrated an insignificant, 44% reduction in plaque with the UltraSonex toothbrush, just slightly better than the 29% reduction observed with a manual toothbrush. Again, stated Tactica, the UltraSonex toothbrush appears to benefit from progressively increasing overnight plaque levels at day 15 through day 30, so there was more plaque to remove and greater plaque reduction at these test points.

The *Forgas-Brockmann study*<sup>4</sup>, which used “standardized oral hygiene instructions” for both the manual brush group and the UltraSonex group, concluded that the UltraSonex toothbrush removed plaque to the same extent that a manual toothbrush did over a 30-day period (the manual toothbrush removed a maximum of 50% of plaque, compared to UltraSonex’s maximum of 52%).

Other studies such as the *Clinical Research Associates study*<sup>5</sup> (“the CRA study”) and the *Roseville study*, found that the UltraSonex toothbrush did not reduce plaque more effectively than the manual toothbrush or other automated toothbrushes.

Similarly, the challenger noted, a *Consumer Reports study*<sup>6</sup> found that the Braun Oral-B Ultra Plaque Remover, not the UltraSonex Plus, was the most effective motorized toothbrush for plaque removal.<sup>7</sup> According to the *Consumer Reports*



article: “faster isn’t necessarily better. Brushes that work at many thousands of strokes or vibrations a second haven’t been proven to be better than others—powered or manual.”

Collectively, argued the challenger, these studies clearly demonstrate that the typical level of plaque reduction for the UltraSonex toothbrush is not 97%, but somewhere between 28%-50%, meaning that it is not better than other toothbrushes (manual or electric).

#### Ultrasonic Penetration/Bacterial Removal claims

Tactica also questioned the validity of the advertiser’s claims that its UltraSonex toothbrush products can: “penetrate deep in the gumline,” “reverse the progression of gingivitis . . .” “interrupt the bacterial process,” “destroy the bacteria,” provide a “substantial reduction in plaque, gingivitis, and bleeding gums” or “dissolve away stains and plaque.”

First, stated the challenger, the elimination of a percentage of bacteria does not equate to an “interruption” or a “reversal” of the natural bacterial process which implies a more progressive effect: that the use of the Sonex toothbrush somehow prevents gingival bacteria from coming into existence and decreases the rate at which gingivitis occurs. Similarly, claims that the UltraSonex toothbrush “dissolv[es] away stains and plaque” overstates what the advertiser actually found: “the teeth were without stain *after a professional dental cleaning.*”

Advertising context aside, the advertiser’s “penetration” test was insufficient support for these claims because: 1) it did not indicate a brushing duration, 2) it lacked a control group, 3) it was not a “crossover” study, 4) there were a limited number of subjects, and 5) the conclusions of the study did not support the dramatic efficacy advertised.

However, even if test is accepted at some level, Sonex’s claims clearly exceed what was examined. As an example, the challenger pointed out that the depths of the sites probed in the test ranged from 4-7 mm, not 9mm. Similarly, the claim that UltraSonex “destroy[s] the bacteria that causes gingivitis and bleeding gums” implies that all of the bacteria is destroyed, when in fact, the study only claims a 21.8% reduction in bacteria.

According to the challenger, the advertiser’s “Japanese study” was equally unpersuasive because it: 1) “was conducted in-vitro, without any correlation analysis to clinical proof, 2) did not account for human salivary factors and anatomic conditions that greatly influence the characteristics of oral cavity bacteria, and 3) did not conclude that there was a reduction in bacteria or that the presence of ultrasound was responsible for breaking up bacterial chains.”<sup>8</sup>

Finally, Tactica dismissed the advertiser’s “orthodontal study” because it only showed the reduction of a single baseline level of gingivitis, not a reversal of increasingly worse gingivitis scores or evidence that the rate at which gums become inflamed is impeded by the use of the UltraSonex.

Conversely, the CRA study shows that the UltraSonex never had a significant effect on bacteria, and was always outperformed by other toothbrushes, including Sonicare, Interplak, Sensonix, and Advantage (manual).

Therefore, the challenger argued, because Sonex has provided no evidence to substantiate its penetration or bacterial removal claims, they should be discontinued.

## II. The SoniPick Flosser<sup>9</sup>

#### Convenience claims

Tactica also objected to claims that the SoniPick Flosser “removes plaque from areas even string floss can’t reach,” “reaches back molars easily,” and is “ideal for removing plaque hiding behind braces, dental implants, and under bridges and crowns,” because the advertiser only provided testimonial evidence, without any objective evidence to support these assertions.

Testimonials, the advertiser pointed out, whether made by a consumer, professional/expert or celebrity, are held to the same requirements as an advertiser’s claim and are therefore subject to the same reasonable basis requirements as all other claims made by the advertiser.”<sup>10</sup>

In addition, Tactica dismissed the advertiser’s puffery defense for claims that “it’s [the SoniPick flosser] ideal” and uses “half the effort of other flossers” because, these phrases “are representations of specific characteristics that can be mea-

sured.<sup>11</sup> The claims asserted by Sonex require that the two products (floss and SoniPick) be tested “head to head” in the same study, under identical conditions, with results clearly favoring the SoniPick flosser. Because such evidence is absent from the record, Tactica argued, the advertiser’s claims are unsupported.

#### Clinical Performance-Plaque Removal claims

Similarly, stated the challenger, the “subgingival deposit removal study” was inconclusive and did not support the claim that “the SoniPick removes plaque deep from within the facial and lingual pockets...” because it examined an irrelevant comparison between the SoniPick flosser and a toothbrush. Consumer would use the SoniPick *in addition* to a toothbrush not *instead* of one. While, the relevant comparison, stated Tactica, is how a toothbrush and the SoniPick perform compared to a toothbrush and floss. It would also be useful to know how the combination of a toothbrush and SoniPick compares to a toothbrush alone.

Moreover, the advertiser’s test only indicated that the SoniPick Flosser cleaned “as deep as 2.53mm.” This level of penetration, stated the challenger, “is not very deep (about one-tenth of an inch)” and it is highly doubtful that the SoniPick cleans the facial and lingual pockets very effectively.

Finally, Tactica questioned claims that the Sonipick is “twice as effective with less than half the effort” or “157% more effective than string floss” because the advertiser’s “clinical evaluation”: 1) appeared to be based on a one day period involving one instance of flossing, 2) the number of participants is unknown, 3) there was no supervision regarding the duration of the flossing, 4) no indication of pre or post-flossing plaque levels and whether or not the study was controlled for handedness (e.g., right-handed patients should have been evenly split into right-side SoniPick and left-side SoniPick groups), and 5) there was no indication as to whether or not the two groups were comparable with respect to gingival health and depth of periodontal pockets at baseline.

For all of these reasons, Tactica requested that NAD recommend that all of the challenged claims for Sonex dental products be discontinued.

#### **ADVERTISER’S POSITION**

At the outset of this challenge, Sonex advised NAD that: 1) “there is a patent litigation in process between Sonex International Corporation and Tactica International Corporation” that will address many of the same issues raised in this challenge, 2) the NAD has examined and approved identical claims before and 3) many of the new claims challenged were created by independent retailers, and will be modified where it is appropriate.

Despite these jurisdictional defenses, Sonex defended its claims on the merits, arguing that all of its claims are supported by virtue of Sonex’s superior toothbrush and flosser design, its testing, NAD precedent and common sense.

#### I. The UltraSonex Ultima and UltraSonex Plus Toothbrush

##### Exclusivity claims

According to Sonex, “ultrasonic” by definition means having a frequency above the human ear’s audibility limit of about 20,000 cycles per second—used for waves and vibrations.<sup>12</sup>

The UltraSonex<sup>®</sup> family of toothbrushes (the Sonex<sup>®</sup>, the UltraSonex<sup>®</sup>, the UltraSonex<sup>®</sup>Plus and the UltraSonex<sup>®</sup> Ultima<sup>™</sup>), owned by Sonex, are the first and only toothbrushes to meet this technical requirement because they both vibrate their bristles at 1.6 MegaHertz and emit ultrasonic waves 1.6 MegaHertz, or 1.6 million cycles per second. In fact, Sonex owns numerous patents for this ultrasonic technology as applied to toothbrush products.<sup>13</sup>

The Ultima<sup>™</sup> toothbrush, it explained, was introduced in the spring of 1999, making it the “newest” UltraSonex<sup>®</sup> toothbrush model. It is the only product that utilizes both sonic (18,000 strokes per minute ) and ultrasonic (1.6 MHz ultrasound) technologies.<sup>14</sup> Therefore, claims that the Ultima is the “newest” and “most advanced” and “only” toothbrush with “dual-wave technology” are accurate.

In response to the challenger’s assertion that the Ultima is a different UltraSonex model that requires separate testing, the advertiser indicated that all UltraSonex toothbrushes are essentially the same because they: 1) emit the same ultrasound, 2) have the same physical features (i.e., identical toothbrush bristles and brush heads), 3) have the same user instructions, and 4) still require the user to provide the brushing motion. The product changes in the Ultima, Sonex continued, are

“small improvements” to enhance the quality, reliability, longevity, and user friendliness of the product. These changes, if anything, will cause the latest Ultima model to perform slightly *better* clinically than the earlier models. Therefore, separate clinical testing for each and every Sonex toothbrush model should not be required.

#### Clinical Performance claims

According to the advertiser, the plaque, bleeding and gingivitis reduction claims are substantially similar, if not identical, to the claims upheld by the NAD in its 1995 Sonex decision. More specifically, Sonex referred to NAD's conclusion that “Sonex has a reasonable basis to claim that it has conducted a clinical study in which bleeding and gingivitis were reduced after 4 weeks of twice daily brushing of 3 minutes, and that after this time, a single brushing with the product resulted in a 97% reduction of plaque, and that gingivitis and bleeding were reduced 60% and 28% respectively.”<sup>15</sup>

Therefore, Sonex argued, it should not be subjected to “double jeopardy,” particularly when it has a “satisfactory” rating with the BBB and has taken several steps to ensure that its advertising complies with NAD's 1995 recommendations.

Nonetheless, Sonex resubmitted the 30 day Terezhalmy study,<sup>16</sup> which examined the effectiveness of the UltraSonex toothbrush on these conditions compared to a manual toothbrush.

The advertiser explained that all of its claims and the conditions of this test are based on the use of the UltraSonex toothbrush according to product instructions; a *requirement* of every FDA qualified study protocol and numerous cases before the NAD. In this study, subjects representative of the general population were divided into two groups and were *instructed* to brush twice daily for three minutes at a time with their assigned brush, as indicated in the UltraSonex toothbrush instructions. Group A used a “manual” Oral-B control brush while Group B brushed with the UltraSonex toothbrush.

Based on the statistically significant results of this 30 day trial, stated the advertiser, the UltraSonex toothbrush: 1) removes 97% (or “virtually all plaque”) plaque according to the *Turesky Index*; 2) reduces bleeding by 60 % according to the *Eastman Bleeding Index*, and 3) reduces gingivitis according to the *Löe and Silness Index*. Therefore, Sonex concluded, its clinical reduction of plaque, bleeding and gingivitis are supported, as they were in the 1995 Sonex decision.

As for the claim, “*no other toothbrush can match that performance*,” the advertiser maintained that such a conclusion follows collectively from the Terezhalmy study which demonstrated the superior performance of the UltraSonex compared to manual toothbrushes; and the Van Der Weijden study, which demonstrated that the best plaque removal score achieved by electronic toothbrushes for the equivalent 3 minute interval was 89% (compared to 97% for UltraSonex).

#### Sonex response to Tactica criticisms

Sonex dismissed Tactica's conclusion that the Van Der Weijden study cannot be compared and actually contradicts the Terezhalmy study because NAD considered both studies and others in 1995, (i.e., the “Geriatric Patient” study and the “six-month” Terezhalmy study), and still upheld the 97% plaque removal claim.

The advertiser also rejected Tactica's assertion that subjects using the UltraSonex toothbrush in the Terezhalmy study somehow benefited from increasing overnight plaque formation because: 1) no known toothbrush can increase overnight plaque formation, 2) the study screened for abnormally high or low plaque level formations, 3) the overnight plaque formation score between day 15 and day 30 was not significantly different, and 4) a “percent” plaque reduction score would benefit from having less plaque to remove not more.<sup>17</sup>

The advertiser explained that higher overnight plaque accumulations later in a study are often attributable to that fact that newly enrolled participants, (without any instruction) tend to brush their teeth extra carefully in the beginning and relax their brushing intensity as time goes on. Therefore, the advertiser explained, there was no brushing test at baseline, and no before and after brushing plaque indexes presented for the baseline. “Between baseline and day 30, subjects were *instructed* to perform oral hygiene twice daily by the assigned method. ... and were *instructed not to* brush their teeth for 12 to 14 hours before each follow up visits so that overnight plaque formation could be assessed.” This is the reason for the instructions given, and why plaque removal measurements are performed only at the follow up visits.



Advertiser's criticism of Tactica's studies

Sonex dismissed virtually all of the studies cited by Tactica because they: 1) did not test the Sonex toothbrush according to product instructions, 2) used atypical populations, 3) were irrelevant to the performance claims at issue,<sup>18</sup> or 4) actually supported the effectiveness of the UltraSonex toothbrush.<sup>19</sup>

Therefore, argued the advertiser, Tactica's reference to other dental studies, in an effort to supplant the conclusions of the 30-day *Terezhalmay study* and undermine the effectiveness of UltraSonex toothbrushes, should be rejected.

Penetration & Sub-Gingival Bacterial Removal claims

With respect to claims that the ultrasound in the UltraSonex toothbrush "penetrates" gingival pockets and "reduces", "reverses", "interrupts", "destroys", "dissolves" gingival bacteria and subgingival flora, Sonex referred to *Webster's College Dictionary* definitions of these terms<sup>20</sup> and then submitted studies to demonstrate the effectiveness of both its toothbrush and ultrasound per se on gingival and subgingival bacteria.

The advertiser explained that, plaque formation is a continuous, never-ending process that occurs in the human oral cavity. A soft plaque film starts to develop within minutes after a cleaning (i.e., after a dental visit and cleaning). This film is the product of subgingival and gingival bacterial flora that colonizes and can ultimately lead to dental and orthodontal disease if left uninterrupted. The soft plaque film on and in-between teeth can also be discolored or stained by food, cigarette smoke, coffee, which is an unavoidable effect of human consumption. Thus, "plaque and/or stain removal" is the effect of interrupting the progress of the bacteria and /or removing the agents that give rise to plaque and stains. It does not imply, as the challenger asserts, the permanent removal of plaque, plaque bacteria or stains on teeth.

Within this context, the advertiser referred to its "subgingival penetration study" (also submitted in the 1995 NAD proceeding), which asked participants to brush for three minutes, twice daily, for four weeks. Patients were examined at screening to detect the presence of gingivitis and diseased periodontal pockets. After the screening test, patients were sent home to continue their normal brushing.

The patients returned four weeks later to establish the baseline for the ultrasonic portion of the crossover test. After the baseline bacteria harvesting and evaluation, the patients were crossed over to the ultrasonic toothbrush, thereby acting as their own control group. They received the other toothbrush and were told to brush according to the instructions in the manual. After four weeks of use of the ultrasonic toothbrush the patients returned for the examination and bacteria harvesting for the ultrasonic portion of the study.

The results of this test, stated the advertiser, demonstrate that "the UltraSonex<sup>®</sup> penetrated the subgingival flora in pockets 4 to 7 mm deep and reduced subgingival plaque by ten fold in 24% of the sites and showed an overall mean plaque reduction of 21.8% for all sites. Because manual toothbrushes cannot reach 4-7 mm below the gumline, "the reduction of the bacterial count within the periodontal pockets demonstrates the ability of the 1.6 MHz ultrasound to effectively penetrate gingival tissue and periodontal pocket 7 mm deep."

This conclusion, Sonex argued, was acknowledged in the 1995 decision in which NAD stated that "Sonex has also shown ...that another test (the "subgingival penetration study") indicated that use of the toothbrush according to directions could reduce subgingival bacteria." Therefore, the advertiser concluded, its claims with respect to the penetration of the gumline and the reduction of subgingival flora are supported.

Sonex dismissed the challenger's criticism the sample size was too small and that its ultrasound studies did not use a crossover group. First, Sonex explained, the test used a sufficient test population to achieve clinical significance; the relevant measuring stick for all studies. In addition, because Sonex did not claim superiority to a particular brush, crossover to another product was not necessary. Instead, the patients selected for the study acted as their own control group because they were "crossed over" to the UltraSonex toothbrush four weeks after they had used their own toothbrush. According to the advertiser, "monadic" or "single group" crossover studies are utilized extensively in biological trials to try to eliminate any possible biological differences between separate control and test groups." Therefore, Tactica's criticisms of the "penetration test" are without merit.

In addition, based on NAD's 1995 recommendations, Sonex conducted additional testing (the "Japanese study" and the "Orthodontal study") to support its claims that its *ultrasound* penetrates the gum tissue and impacts the periodontal



bacteria within the gum pockets.<sup>21</sup> These studies, Sonex explained, were purposefully designed so that “the only variable is the presence or absence of ultrasound, thereby demonstrating the effect of ultrasound per se.”

According to Sonex, the “Japanese study” (“in-vitro”) demonstrated that the ultrasound emitted by UltraSonex breaks up the chains and colonies of *S. mutans* and damages bacteria cells, providing a reasonable basis for the conclusion that UltraSonex “destroys” bacteria and bacterial colonies.

Similarly, stated the advertiser, the “orthodontal study,” “a randomized, double-blinded, placebo-controlled clinical trial,” of 48 patients reported a clinically significant reduction in gingivitis and bleeding when the real UltraSonex was compared to placebo (an UltraSonex brush without the effects of ultrasound). It also showed even greater (83%) bleeding and (47%) gingivitis reductions than those established in the *Terezahalm study*. Here, the advertiser explained, patients were assigned a toothbrush and were instructed to brush for three minutes, once in the morning and once at night, for the twelve week duration of the test.

Given these new findings, the claims pertaining to the effectiveness of ultrasound per se are supported.

## II. The SoniPick Flosser

### Convenience / Plaque Removal claims:

According to the advertiser, claims that the SoniPick flosser: “reaches molars easily,” “goes where string floss can’t to get rid of all of your plaque,” “shake[s] out even the most stubborn plaque-no matter where it is hiding” and is “ideal for removing plaque behind braces, dental implants, and under bridges and crowns are substantiated by testimonial accounts and the SoniPick Flosser design, which has obvious advantages over traditional dental floss.<sup>22</sup> Collectively, stated Sonex, the phrase “it’s ideal” embodies all the advantages that the SoniPick flosser provides to users and should be considered “puffery”.

The advertiser explained that its product can be held in one hand and use bristles with ultrasound to clean between teeth. Unlike string floss, it does not require a push and pull motion to clean. The user merely has to place the bristles of the pick in the desired cleaning area.

It also provided (in confidence) a “subgingival deposits removal study”, which it asserted, demonstrates the capability of the SoniPick™ to clean plaque from facial and lingual pockets 3 mm deep within the gumline. Because string floss cannot penetrate as deep or clean facial and lingual pockets, the advertiser contended, claims that the SoniPick™ removes plaque from deep within the facial and lingual pockets” and “areas even string floss can’t reach” are truthful and accurate.

In addition, Sonex argued, the effectiveness of the SoniPick™ is further demonstrated by an “independent clinical comparison,” which showed that regular string floss removed only 23% of plaque, but SoniPick™ removed 59%.” Therefore, claims that the SoniPick™ is “twice” or “157% more effective” than string floss are substantiated.

### Cost claims

According to Sonex, the claim “costs just a fraction of those automatic flossers” refers to the only other automatic flosser on the market, the Braun Oral-B Interclean. The Braun Interclean flosser retails between \$50.00 and \$75.00 dollars. The SoniPick™ in contrast, retails for between \$29.00 and \$35.00 dollars, which is approximately one third to one half or a fraction of the cost of the Interclean. Therefore, at the time this claim was disseminated to the public, it was accurate.

For all of these reasons the advertiser requested that the Tactica challenge be dismissed.

## DECISION

In the instant challenge NAD considered whether the advertiser’s evidence (collectively) supported the challenged exclusivity, clinical performance, penetration, bacterial reduction, convenience and cost claims made for its dental products (the UltraSonex Ultima toothbrush and SoniPick flosser).

According to the challenger, none of these claims are substantiated because: the UltraSonex Ultima is not the newest, most advanced toothbrush you can buy; and because the advertiser’s testing: 1) was not conducted on the Ultima, 2) failed to comply with well established controls, 3) lacked peer review, 4) did not support what is claimed, and 5) is contradicted by more reliable clinical performance tests.

In contrast, Sonex argued that: 1) its dental products (The Ultima toothbrush and SoniPick) are in fact the “newest,” “most advanced,” “convenient,” “ideal” dental technology you can buy, 2) there is no material performance difference between the Ultima toothbrush and preceding models (i.e., the UltraSonex Plus), 3) many of its claims and tests were reviewed and accepted by the NAD in its 1995 Sonex decision, 4) its testing and superior product designs effectively support the performance of its products with respect to plaque, bleeding, gingivitis, penetration, subgingival bacteria and convenience, and 5) Tactica’s testing is irrelevant and/or fatally flawed.

Given these dramatically different views, NAD first examined the challenged claims in the context of the challenged advertisements to determine the reasonable messages conveyed. Based on those findings, NAD evaluated the advertiser’s evidence to determine whether or not it provided adequate support.

Moreover, because advertising for an earlier version of Sonex toothbrushes had been subject to previous NAD review; NAD also considered, whether or not there was a “material difference” between the UltraSonex toothbrush currently on the market and the product reviewed in 1995; and to what extent, if any, NAD’s 1995 Sonex decision controlled in this instance.

#### Exclusivity claims

The advertiser provided written verification that its Sonex toothbrush models are the only brand of toothbrushes that meet the technical definition of “ultrasonic” because they both vibrate their bristles at 1.6 megahertz and emit ultrasonic waves 1.6 megahertz. The advertiser owns several patents involving the application of ultrasound technology to toothbrush and flosser products. These patents afford the advertiser the exclusive right to exclude competitors from making, using or selling this technology. Accordingly, NAD concluded that the advertiser had a reasonable basis for claims that UltraSonex toothbrushes are the “world’s only ultrasonic toothbrush”.

In addition, NAD accepts as true the advertiser’s assertion that the Ultima toothbrush (the latest Sonex model) incorporates both ultrasonic and sonic (a vibrating) components. Absent evidence that any other toothbrushes meet the technical definition for ultrasound (1.6 megahertz), NAD also concluded that the advertiser has a reasonable basis for its claims that the Ultima is the “first and only toothbrush to combine ultrasound and high speed frequency,” or “dual wave technology.”

NAD also accepts the advertiser representation that at the time of its introduction in 1999, the Ultima product was in fact “new”. Nevertheless, NAD cautions the advertiser not exceed the 6-month limitation that accompanies the use of the term “new” in advertising. A limitation that, NAD notes should, by now, be in full effect.

These conclusions with respect to the Ultima, however, give rise to a greater question: Is the Ultima materially different from other UltraSonex toothbrushes to an extent that requires new product performance testing?

While the Ultima toothbrush (Sonex’s latest model), has an added vibrating, sonic component, it shares the same: 1) physical features (i.e., identical toothbrush bristles and brush heads), 2) user instructions, 3) ultrasonic frequency and 4) use requirements (that users provide the brushing motion) as all other UltraSonex toothbrushes. Given these substantial similarities, NAD found no basis to believe that the “sonic” feature would prevent the Ultima from providing the same level of performance demonstrated by the UltraSonex Plus toothbrush. NAD agreed with the advertiser that, if anything, this feature would enhance the Ultima performance capability in comparison to the UltraSonex Plus. Therefore, NAD concluded, the performance testing conducted on the UltraSonex Plus model, is relevant to UltraSonex Ultima performance as well.

However, to ensure accuracy, NAD recommends, that claims referring to Ultima product performance, be modified to either refer to UltraSonex toothbrushes generally or the specific UltraSonex model tested.<sup>23</sup>

#### Clinical performance claims

It is well established that an advertiser is responsible for all reasonable interpretations of its claims, not just those messages the advertiser intended to convey.<sup>24</sup> When an advertiser makes “clinically proven” superiority claims for its product, it has the substantial burden of supporting those claims with product testing, conducted under consumer relevant conditions, that is probative of the advertising claims.<sup>25</sup> Such testing should also follow industry-accepted protocols and stand on its own merit before it can be used alone, or in conjunction with other evidence, as support for a claim.<sup>26</sup> Moreover, claims based on clinical studies should be no broader than the conclusions drawn from the study and any material limitations of a claim must be adequately disclosed.<sup>27</sup>



As the advertiser correctly pointed out, in a prior proceeding, NAD reviewed clinical performance claims and testing (including the 30 day *Terezhalmy study*) that pertained to an earlier version of Sonex toothbrushes, and determined that the claims were accurate, provided that they were accompanied by a complete disclosure of the salient details of the supporting test.

Specifically, in 1995, NAD recommended that the advertiser disclose that: 1) the benefits followed 4 weeks (or 30 days) of twice daily 3-minute brushings; 2) the plaque reduction was the before and after difference of a single brushing; 3) clinical references in connection with these claims allude to a single test (not tests or studies) as there was only one controlled clinical, and 4) when claims regarding clinical proof of "safety and effectiveness" are combined in a single claim (thereby referring to tests), the claim should not imply, by its context, that more than one controlled effectiveness clinical has been completed."<sup>28</sup>

After a careful review of the evidence produced in the present inquiry, NAD determined that the test conditions, protocols and claims with respect to plaque (97%), gingivitis (60%) and bleeding (28%) reduction are identical to those examined in the 1995 inquiry.<sup>29</sup> Pursuant to section 3.7 of the *NAD/NARB Procedures*, NAD is barred from re-examining advertising that has previously undergone NAD review absent an extraordinary change in circumstances. Based on the record before it, NAD concluded that no such extraordinary circumstances exist here.

The dental industry accepts as reliable a variety of different plaque removal tests with significant variations in protocols and grading criteria. For example, some tests focus on a "one-time" brush evaluation while others evaluate performance over longer periods. Some tests utilize a cross over design while others do not. Many tests differ in terms of brushing abstention periods before testing, the inclusion/exclusion of dental aids (mouthwash or toothpaste) and the index used to grade plaque removal. The results themselves can introduce a subjective element because scores are based on the visual assessment of a grader. Thus, it is quite possible for two competitors to conduct "industry accepted" plaque removal tests and arrive at different results.<sup>30</sup> The studies submitted by the challenger presented a different set of test conditions, thereby reaffirming this proposition.

What is relevant here is how well the tests reflect the prescribed product usage and what is claimed. Therefore, NAD did not revisit the reliability of the 30-day *Terezhalmy study*; but rather looked to whether the challenged claims *complied* with the specific recommendations articulated in the 1995 decision.

In most of the new advertisements, NAD noted, the advertiser did revise its claims to follow NAD's 1995 recommendations. There are several advertisements where the 97% plaque, 60 % bleeding and 28% gingivitis reduction claims are accompanied by language disclosing that the results were achieved "after four weeks" or "30 days" "in a single brushing" after subjects were instructed to brush "twice daily" for "three minutes."

However, some of the advertisements in the challenged campaign did exhibit some deficiencies. For example, there are claims that the Ultima "eliminates 97% plaque with *each* three minute brushing," and "*every* time you brush." These claims could reasonable be interpreted to mean that 97% plaque removal is routinely achieved, when in fact, the supporting test was based on a single measurement taken after in a single brushing, after 30 days of use. In other instances, the clinical reduction claims are not accompanied by any disclosure of the salient details of the test.

NAD also had serious concerns as to whether the claim: "*No other toothbrush can match that (97%) performance*" could be sustained without "head to head" testing between the UltraSonex toothbrush and other competitive electronic toothbrushes (not just a manual toothbrush) under the same conditions. As constructed, the claim is likely to create the impression that other toothbrushes (including electronic toothbrushes) were involved in the study where the 97% UltraSonex plaque reduction was achieved, when that is not the case.

In addition, it is unclear whether the 74% and 67% reduction in gingivitis claims, based on a six-month evaluation, refer to the same or two different six-month studies.

While NAD accepts the advertiser's representation that independent retailers created some of these claims, an advertiser that provides product information to a catalog retailer has the obligation to insure that the product claims made in the catalog are supported.<sup>31</sup>

For these reasons, NAD recommends that the advertiser: 1) modify its claims to remove any implication that the advertised results are achieved in multiple instances, 2) ensure that all of the pertinent conditions of the test are clearly and



conspicuously disclosed in close proximity to any clinical performance claims relying on the *Terezhalmay study*, 3) discontinue the claim: "no other toothbrush can match that performance" unless and until the Ultima and electronic toothbrushes are evaluated "head to head," under the same test conditions and produce results that support the claim; and 4) ensure that its gingivitis reductions claims (after six months) are clearly and consistently reported.

*Ultrasonic Penetration/Bacterial Removal claims:*

As the advertiser correctly points out, NAD's 1995 decision states "another test (also submitted in this inquiry) indicated that use of the toothbrush according to directions could reduce subgingival bacteria." The advertiser also resubmitted the study that was the basis for this conclusion and referred to *Webster's College Dictionary* to establish that advertising claims with terms such as "removes", "destroys" and "dissolves", were used in a manner consistent with the testing.

While use of a dictionary is certainly one way to lend support an advertiser's position as to what specific words will mean to consumers, advertising claims must be examined in context, and the advertiser must be able to support all reasonable messages conveyed by its claims.

It is undisputed that plaque, bleeding and gingivitis are linked to the accumulation of gingival and subgingival bacteria. The formation of bacterial plaque is a natural, continuous process aided by activities such as eating, drinking, smoking, etc. This bacterium grows in colony formations, which if not controlled, or interrupted in some way, can release toxins that lead to severe dental problems. Consumers typically brush at least once a day as a protective/preventative measure, anticipating that plaque and bacteria will otherwise accumulate.

The study previously submitted in 1995, established that UltraSonex toothbrushes can be effective on subgingival plaque approximately 4-7mm deep, and can reduce subgingival (an overall 21% reduction for all sites tested). Therefore, consistent with the reasons articulated in the 1995 decision, NAD determined that the advertiser could theoretically support claims that its UltraSonex toothbrushes "penetrate 4-7mm below the gum line" and "attacks" "interrupts," "disrupts," and "destroys" bacterial formations.

However, most if not all the penetration and bacterial effectiveness claims challenged here assert the effectiveness of *ultrasound per se*. NAD notes that, in the 1995 Sonex decision, it recommended that "Sonex discontinue all pocket and gum penetration claims in its advertising, both verbal and non-verbal (the tooth drawings depicting "ultrasound waves" going through gum tissue, pockets and teeth), until such time as it has completed a controlled study evidencing that effect by the *ultrasound per se*."<sup>32</sup> In this challenge, NAD examined whether Sonex's new evidence supports the claims that its ultrasonic component "penetrates 4-7mm below the gum line" and "attacks" "interrupts," "disrupts," and "destroys" gingival and subgingival bacteria.

As support, the advertiser produced two studies that isolated and examined the effects of its ultrasonic component on bacterial forming plaque. After careful review, NAD concluded that both studies offer some support for the advertiser's position that ultrasound has a disruptive effect on plaque forming bacteria. For example, the "Japanese study" suggests that ultrasound held 5mm away from the test tooth enamel "ruptures bacteria chains," "damages bacterial cell structure" and "inhibits the adherence of *S. mutans* on enamel surface." Similarly, the "Orthodontal study," showed a statistically significant reduction in bleeding and gingivitis (based on a 12 week evaluation) compared to the placebo toothbrush group (using just a manual brushing method). For this reason, NAD determined that the advertiser had a reasonable basis for its claims that the ultrasonic component of its toothbrush "cleans teeth and gums," "interrupts the bacterial process" and "disrupts the bacteriological activity that is at the root of tooth decay and gum disease."

However, NAD was not persuaded that either test proved that the ultrasonic component of the advertiser's toothbrush: 1) *destroys* plaque, 2) is effective against subgingival plaque (5mm or 9mm), or 3) "is far more effective than mechanical brushing because it disrupts the bacterial process."

The "Japanese study," was an in-vitro analysis, conducted using simulated enamel blocks, brain/heart infusion broth, and a test bacteria-*S mutans* 10449. While laboratory studies can provide valuable insights into product performance capability, absent any correlation to clinical results, NAD was hesitant to conclude that the ultrasound would perform the same way under consumer relevant conditions,<sup>33</sup> or that rupturing, inhibiting and/or damaging bacterial cells on an enamel surface is equivalent to eradicating ("destroying" or removing them) them. The bacteria, temporarily disrupted/interrupted by ultrasound, are still present and can re-synthesize to a toxic level quicker than if it had been removed.

Similarly, the orthodontal study, which compared an activated ultrasonic toothbrush and deactivated placebo brush *did not* show a statistically significant reduction in overnight plaque. Moreover, because mechanical brushing also disrupts bacterial progression by sweeping away plaque, the contribution of ultrasound on plaque was unclear.<sup>34</sup>

In addition, NAD noted, neither of the ultrasound studies examined sub gingival reductions, or isolated and compared the two cleaning methods (i.e., manual cleaning vs. ultrasound cleaning) as suggested by the claim: "ultrasound is far more effective than mechanical brushing." At best, NAD can conclude from the orthodontal study that ultrasound and mechanical brushing *together* can reduce bleeding and gingivitis more effectively than mechanical brushing alone.

Consequently, NAD recommends that the advertiser discontinue claims that its *ultrasonic* feature: 1) *destroys* plaque, 2) is effective against *subgingival* plaque (5mm or 9mm), or 3) "*is far more effective* than mechanical brushing because it disrupts the bacterial process; unless and until it obtains reliable evidence that specifically examines and confirms these assertions.

## II. The SoniPick Flosser<sup>35</sup>

### Convenience / Plaque Removal claims:

It is well established that testimonials, whether made by a consumer, professional/expert or celebrity, are subject to the same reasonable basis requirements as any other claims made by the advertiser. Consequently, an advertiser must produce a separate, objective basis to support such claims.<sup>36</sup> In addition, for a claim to constitute "puffery" it has to be couched in opinion in such a manner than consumers would not believe the claim to be verifiable or rely on it as truthful.<sup>37</sup>

In this instance, NAD determined that the claims were not puffery and therefore, the advertiser needed to provide an objective basis of support demonstrating that the SoniPick Flosser was more convenient and efficient than string floss, and "ideal for consumers with braces, bridges, crowns and hard to reach places". The advertiser contended that a simple observation of the SoniPick Flosser's design and demonstration of how it functions provides a reasonable basis for its claim. NAD agrees. Unlike string floss which must be held at both ends and requires the user to provide a back and forth pulling motion, the SoniPick can effectively reach interdental spaces by simply placing the tip or "pick" in the desired cleaning area.

The SoniPick is particularly convenient for hard to reach places (i.e., back molars) and for consumers with braces, bridges, crowns and dental implants, because it doesn't require the user to feed string through or underneath areas where there may be orthodontal work. In addition, the pick is more convenient in hard to reach places such as the back of the mouth because, again, it does not require the user to place the floss in between teeth with both hands. Therefore, NAD concluded that the advertiser had a reasonable basis for its "convenience claims" with respect to its SoniPick Flosser.

However, NAD determined, claims asserting that the SoniPick flosser "removes plaque deep within facial and lingual pockets," is "157 % more effective than string floss" and removes "59% between teeth plaque compared to 23% with string floss" require more than a mere showing of convenience as support.

NAD examined the advertiser's "subgingival deposits removal study" and determined that the SoniPick could clean facial and lingual pockets below the gumline. In reaching this conclusion, NAD found the manual toothbrush comparison to be instructive because the SoniPick Flosser, like a toothbrush, has a handle, is held in one hand, and uses a "bristle head" to clean.

In addition, NAD found that the "independent clinical study" supported the SoniPick "effectiveness" claims because it used a "split mouth" where subjects would floss with string on one half of their mouth at selected tooth sites and the SoniPick on corresponding teeth on the other side of the mouth. The study compared over 75 data points, and broke down by toothsite, the percent of plaque removed by each method. Based on the results, NAD determined that the advertiser had demonstrated 59% removal for the SoniPick as compared to 23% removal for string floss. Because 59% is "twice" or "157% more effective [than string floss]" NAD concluded that these claims had been substantiated as well.

However, to avoid the potential for any consumer confusion, NAD recommends that some details about the test method be disclosed, (i.e. based on a split mouth comparison, etc.) so that the reader can understand the conditions under which these results were achieved.



Cost/Saving Claims

It is well established that pricing and savings claims must continually be evaluated and updated to ensure that they accurately reflect the ever-changing prices in the marketplace.

The advertiser represented (and it was not disputed by the challenger), that the Braun InterClean flosser retails for between \$50.00 and \$75.00 dollars. The SoniPick™ in contrast, retails for between \$29.00 and \$35.00 dollars, which is approximately one third to one half or a fraction of the cost of the InterClean. Based on these figures, NAD determined that a claim that the SoniPick flosser “costs a fraction” of what InterClean costs is true.

However, the claim “those other automatic flossers,” is plural and therefore can reasonably be interpreted to apply to more than one flosser, including electronic flossers that consumers may mistakenly believe to be “automatic”. To avoid conveying this inaccurate message, NAD recommended that this cost comparison be limited to the Braun InterClean. In addition, NAD cautions the advertiser to monitor its price/savings claims in the future to ensure that they are kept current and accurate.

**CONCLUSION**

Exclusivity claims: NAD determined that the advertiser had a reasonable basis for claims that UltraSonex toothbrushes are the “world’s only ultrasonic toothbrush”, and that the Ultima is the “first and only toothbrush to combine ultrasound and high speed frequency,” or “dual wave technology.” However, to ensure accuracy, NAD recommends that product performance claims for Ultima, based on testing of other models of UltraSonex toothbrushes, be modified to either refer to UltraSonex toothbrushes generally or the specific UltraSonex model tested.

Clinical Performance (Plaque, Gingivitis, Bleeding Reduction) claims: NAD recommends that the advertiser modify its current claims to comply with the recommendations set out in NAD’s 1995 Sonex decision. This includes; 1) removing any implication that the advertised results are achieved in multiple instances, 2) ensuring that all of the pertinent conditions of the test are clearly and conspicuously disclosed in close proximity to the clinical performance claims relying on the Terezhalmy study, 3) discontinuing the claim: “no other toothbrush can match that performance” unless and until the Ultima and electronic toothbrushes are evaluated “head to head,” under the same test conditions and shown to perform better, and 4) ensuring that its gingivitis reductions claims (after six months) are clearly and consistently reported.

UltraSonic Penetration/Bacterial Removal claims: NAD concluded that the advertiser’s evidence was sufficient to support its claims that the ultrasonic component of its toothbrush “cleans teeth and gums,” “interrupts the bacterial process” and “disrupts the bacteriological activity that is at the root of tooth decay and gum disease.” However, NAD concluded that the advertiser’s claims that its *ultrasonic* feature 1) *destroys* plaque, 2) is effective against *subgingival* plaque (5mm or 9mm); and/or 3) “is far more effective than mechanical brushing because it disrupts the bacterial process; are overly broad and recommended that they be discontinued unless and until it obtains reliable evidence that specifically examines and confirms these assertions.

Convenience/Effectiveness claims: NAD concluded that the advertiser provided a reasonable basis for its “convenience claims” for its SoniPick Flosser, and claims that the SoniPick can clean facial and lingual pockets below the gumline, where string floss can’t reach”, “can achieve 59% plaque removal compared to 23% for string floss” and that the SoniPick product is “twice” or “157% more effective [than string floss]”. However, to avoid the potential for any consumer confusion, NAD recommended that some details about the test method also be disclosed, (e.g., based on a split mouth comparison, etc.) so that the reader can understand the conditions under which these results were achieved.

Cost claims: NAD recommended that the claim “costs a fraction of those automatic flossers” be modified to limit the cost comparison to the Braun InterClean. In addition, NAD cautioned the advertiser to monitor its price/savings claims in the future to ensure that they are kept current and accurate

**ADVERTISER’S STATEMENT**

Sonex International Corporation is pleased that the NAD found its advertising claims principally substantiated. Sonex’s advertising claims are based on scientific, clinical and laboratory studies by Universities and independent research organizations. It is gratifying indeed that during its careful review of the numerous claims challenged, the NAD has recognized and accepted the validity of these scientific studies, and the resulting claims.

Sonex will take into consideration the NAD’s recommendations and the clarifications suggested in future copy. Nevertheless, Sonex already includes the pertinent clarifications in its own advertisements, the same were not always included in



some catalog publications. Mindful of its obligation to ensure that the product claims made by independent catalog publications also include all pertinent clarifications, Sonex will renew its efforts to instruct its independent retailers and catalogs accordingly. Sonex is pleased to have participated in the NAD self-regulatory procedures. (#3656 NFV, closed 6/1/00)

## NOTES

1. Other models mentioned included: the hyG Ionic toothbrush, manufactured by Dyna-Dental, and the Dual Action Broxo Perio Brush, manufactured by Health Care/PerioSystem.
2. The instructions to the UltraSonex group read in part, "It is critical that the gums and gingival pockets between the gums and your teeth are reached by the ultrasonic waves. The bristles should be positioned over the junction of the gums and teeth."
3. For example, stated the challenger, assume that both toothbrushes can remove all but 1 unit of plaque on the 0-5 *Turesky Plaque Index*. With an overnight plaque level of 2, the manual toothbrush's percent reduction score would be  $(2-1)/2 = 50\%$ . If the UltraSonex group had an overnight plaque level of 3, its percent reduction score would be  $(3-1)/3 = 67\%$ .
4. "The Effects of an Ultrasonic Toothbrush on Plaque Accumulation and Gingival Inflammation," (1998).
5. See the "Automated Toothbrush Comparison Statistical Report" published in 1998.
6. "How Ultrasonic and Motorized Brushes Compare with Elbow Grease
7. Among normal patients, the UltraSonex removed 81% of plaque, compared to 83% for the Braun Ultra Plaque Remover. Among handicapped patients, the UltraSonex removed 56% of plaque, compared to 57% for the manual Oral-B Advantage and 56% for the Braun Ultra Plaque Remover.
8. The challenger pointed out that the test "results showed that ultrasound has *some* influence on *S. mutans* cell wall and intracellular components suggesting that ultrasound inhibits the adherence of *S. mutans* on enamel surface."
9. NAD notes that some of the original claims challenged were excluded from consideration due to pending patent litigation between the parties concerning the Sonex SoniPek Flosser product.
10. Sonex International Corporation (UltraSonex Ultrasonic Toothbrush), NAD Case Reports-February 1995. Likewise, NAD has stated that "testimonials and anecdotes do not substantiate claims." Global Travel International, Inc. (Global Trade International), NAD Case Reports-October 1998.
11. The challenger referred to past NAD decisions to illustrate the distinction between puffery and verifiable claims. Global Travel International, Inc. (Global Trade International), NAD Case Reports-October 1998.
12. Webster's College Dictionary definition of "ultrasound".
13. The advertiser explained that all of the other toothbrushes on the market, such as the Braun® Oral-B 3D Ultra, Broxodent, InterPlak, Butler, American Dentronics, Krups, Norelco, Sonicare, Teledyne Sensonic are best described as "sonic" toothbrushes because they operate at a speed of 31,000 strokes per minutes or less (258 cycles per second or below, with two strokes equaling one cycle), well below the 20,000 cycles per second or more which are ultrasonic."
14. The advertiser explained that all other toothbrushes mentioned by the challenger were on the market before the Ultima™ and without exception, utilize either a single electric motor (Braun® Oral-B 3D Ultra, Broxodent, InterPlak, Butler, Krups, and Norelco, etc.) or a single electric magnet (Sonicare and the Teledyne Sensonic) to generate their sonic waves.
15. Sonex International Corporation (UltraSonex Plus toothbrush) NAD Case Reports—February 1995, p. 11, 14.
16. Terezhalmay study, et al. entitled "Clinical Evaluation of the Efficacy and Safety of the UltraSonex Ultrasonic Toothbrush: A 30-day Study" (the "Terezhalmay study").
17. The advertiser stated by way of example, if both brushes could remove 1 unit of plaque, and the UltraSonex test had a plaque level of three while the plaque formation was a level two for the manual brush, the % removal for the manual brush would be 50% while the UltraSonex toothbrush would only show 33% removal. Therefore the advantage would be for the manual toothbrush.
18. Sonex's main criticisms were: 1) the test did not follow the 3 minute brushing protocol (the *CRA study*-2 minutes, Roseville study-2 minutes), (2) the test used an atypical population (the *CRA study*-handicapped population, Roseville study-small sample size, the *Foras-Brockmann study*-extremely high bleeding and gum sensitivity, the *Ho Niederman study*-orthodontics patients), 3) the test cited was for a longer or shorter duration than the 30 days specified by the advertising (the Cronin study—90 days of brushing) and 4) the test was anecdotal, not accounting for full mouth measurements ( *Consumer Reports study*-one surface of six teeth) and "plaque removal did not figure into the overall score").
19. For example, the six month *Terezhalmay study*, submitted by Sonex in 1995, concludes that "the ultrasonic toothbrush significantly reduced overnight plaque formation after prolonged use (6 months)." This study, the advertiser pointed out, did not contradict the 97% plaque removal established by the *Terezhalmay study* because it had a different measurement criteria: (overnight plaque formation-Six Month study, not plaque removal in a single brushing-Terezhalmay). Similarly, the "Whitmyer, Terezhalmay, Miller Study" (a.k.a. "the Geriatric Study") also provided by Sonex in 1995, verifies the effectiveness of the ultrasound in the UltraSonex toothbrush, because daily plaque removal increased from 29% with the manual toothbrush to 44% (a significant improvement) with the UltraSonex toothbrush. The lower plaque reduction scores, in general, were due to the fact that an elderly population with limited dexterity was used for the study. However, stated the challenger, the statistically significant disparity between the two groups was due to the ultrasound component.
20. reversal: "an act or the process of reversing; opposite or contrary to a previous condition; to change to the contrary; to cause to go in the opposite direction." interrupt: "to break the uniformity or continuity of; to get in the way of; to cut off; obstruct;" destruct or destroy: to ruin the structure,

organic existence, or condition of; to put out of existence; kill; substantial "significantly great," not imaginary or illusory; real; true; considerable in quantity; significantly large; dissolve: "to cause to disperse or disappear", "destroy", "disintegrate"; etc.

21. Sonex International Corporation (UltraSonex Plus toothbrush), *NAD Case Reports—February 1995*, p. 11, 16.

NAD requested that: "Sonex discontinue all pocket and gum penetration claims in its advertising, both verbal and non-verbal (the tooth drawings depicting "ultrasound waves" going through gum tissue, pockets and teeth), until such time as it has completed a controlled study evidencing that effect by the ultrasound *per se*."

22. For example, stated the advertiser, the Hygienist, clearly stated that "The SoniPick™ is an effective tool to "deplak" bridges, crowns, implants, braces, as well as standard dentition." The Dentist also provides favorable support stating that: "Our office has seen remarkable improvements in the oral health in those patients who use the SoniPick™." Consumers who have used the pick have indicated that: "...SoniPick™ is the most effective, effortless and gentle cleaning tool there is — much better than floss, 'bottle brushes', irrigation syringes or wooden toothpicks. I use the larger bristles to clean around and between the teeth and the small bristle cleans the furcation of the molars where no other device can reach." Other consumer comments include: "My gum improved 100%," and "My dentist was so impressed with my last exam (I told him about the SoniPick) that he purchased several himself!"

23. See Sonex International Corporation (UltraSonex Plus Toothbrush), *NAD Case Reports—February 1995*, headnote: "Comparative claims require substantiation that involved the comparative products mentioned or alluded to."

24. The Procter & Gamble Company (Ultra Joy Dishwashing Liquid), *NAD Case Reports—June 1998*, p. 132, 137;

Chanel, Inc. (Day Lift Refining Complex), *NAD Case Reports, January 1994*, (head note); "An advertiser must be able to support all implications of a claim, even if some implications are unintended."

25. See Clairol, Inc. (Ultress Hair Colourant), *NAD Case Reports—February 1996*, p.24; NAD's evaluation had to focus on "the value of these test results as they pertain to the communication of the comparative benefit of product use, i.e. 'best conditioning';" Bogdana Corporation (Cholestaway), *NAD Case Reports—July 1995*, pp.110, 112; studies though soundly conducted, do not support the dramatic efficacy claims made in the infomercial.

26. Bio-Foods, Inc. (Balance Nutrition Bars), *NAD Case Reports—February 1998*, (head note), p.6; Revlon Consumer Products Corporation (Colorsilk and Frost & Glow Hair Coloring Products), *NAD Case Reports—January 1999*, p. 358, 364.

27. Sonex International Corporation (UltraSonex Plus Toothbrush), *NAD Case Reports—February 1995*, p.11.

28. *Id.*, p.14. "NAD finds that Sonex has a reasonable basis to claim that it has conducted a clinical study in which bleeding and gingivitis were reduced after 4 weeks of twice daily brushing of 3 minutes, and that after this time, a single brushing with the product resulted in a 97% reduction of plaque, and that gingivitis and bleeding were reduced 60% and 28%, respectively."

29. The claims specify the same level of plaque 97%, gingivitis 60% and bleeding 28% reductions and advertiser relies on the same test to support these claims.

30. See Oral-B Laboratories (Oral—B Cross Action Toothbrush), *NAD Case Reports—October 1999*, p.242, 250; Braun Inc., (Braun Oral B Plaque Remover), *NAD Case Reports—February 1996*, p. 8,18. "NAD has been shown three valid clinical considering the Braun and Optiva products that have come to different results, but not because any was invalid, or one or more was shown to be better than the others. They measured different characteristics: the amount of plaque removed at a given time following six months of product use as measured by one index; the amount of plaque removed by a dental professional after a short study using a different index, and the amount of plaque that was on teeth following overnight accumulation, and 'accumulation' following eight weeks of product use."

31. Sonex International Corporation (UltraSonex Plus Toothbrush), *NAD Case Reports—February 1995*, p.11, 16.

32. The distinction is material. NAD notes that the challenger in the 1995 decision demonstrated that manual brushes can also penetrate below the gumline, leaving open the question leaving open the question of how effective is the ultrasound *per se* at removing subgingival plaque.

33. The record indicated that there are over 166 bacterial species and subspecies in periodontally healthy patients.

34. All three of the above approaches may be obtainable by mechanical means since repeated disruption of plaque maturation could result in a plaque with lower levels of certain bacterial groups. Advertiser's Exhibit 6.

35. NAD notes that some of the original claims challenged were excluded from consideration due to pending patent litigation between the parties concerning the Sonex SoniPick Flosser product.

36. See Federal Trade Commission Guidelines, *Consumer Endorsements*, § 255.2 (a) and (c).

37. Global Travel International, Inc. (Global Trade International), *NAD Case Reports—October 1998*.